

## **REMARKS**

Reconsideration of this application and reexamination of the claims in view of the amendments and remarks presented herein are respectfully requested.

### **I. Status of the Claims**

Applicants have cancelled claims 96, 99, 106-118, 141, and 142 without prejudice to, or disclaimer of, the subject matter of the cancelled claims. Applicants submit that this amendment is being made to allow for the remaining claims to issue in a timely manner and is not being made out of acquiescence to any rejection. Applicants reserve the right to prosecute the same or similar claims in a continuation application.

Applicants have amended claim 100 to incorporate the limitations of cancelled dependent claim 106. Applicants submit that this amendment is being made to allow for amended claim 100 to issue in a timely manner and is not being made out of acquiescence to any rejection of claim 100. Applicants reserve the right to prosecute a claim that is the same as or similar to unamended claim 100 in a continuation application.

Applicants have amended claim 101 to overcome an objection to the wording of the claim by the Office. Applicants submit that this amendment merely serves to render the claim even more clear, and that, in view of this amendment, the objection to claim 101 is moot. Applicants request that the objection to claim 101 be withdrawn.

The amendments to the claims do not introduce new matter.

With entry of this amendment claims 97, 98, 100-105, 119-140, and 143-146 are pending.

**A. Request for Rejoinder**

In the Office Action, the Examiner withdrew claims 108-146 from consideration, stating that they are drawn to a nonelected invention. Applicants submit that the claim amendments and remarks provided herein, and the Deposit Declaration filed herewith, place claims 97, 98, and 100-105 in condition for allowance. Applicants request that claims 119-140 and 143-146, which each depend from one of product claims 97-105 be rejoined to claims 97, 98, and 100-105 at this time. See M.P.E.P. 821.04.

**II. Double Patenting**

The Office provisionally rejected claims 96-107 under the judicially-created doctrine of obviousness-type double patenting, as allegedly unpatentable over claims 205 and 8 of Application No. 10/240,102. Applicants note that a Notice of Allowance has not been issued in the '102 application and that, indeed, no Office Action has yet been issued. In view of these circumstances, Applicants request that the Office withdraw this rejection for obviousness-type double patenting and allow claims 97, 98, 100-105, 119-140, and 143-146 to issue in the instant application. Applicants submit that any issue relating to obviousness-type double patenting may then be addressed, if appropriate, in the '102 application.

**III. Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Office rejected claims 99-105 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicants have canceled claim 99 herein, rendering this rejection moot as to claim 99.

Regarding claims 100-105, the Office asserted that a person of ordinary skill would not know the metes and bounds of a "natural activator". (Office Action at page 7.)

Applicants submit that the amendment of claim 100 to recite “wherein the first and the second fragments of the catalytic domain of the *Bordetella pertussis* adenylate cyclase (CyaA) *in vitro* functionally interact with calmodulin (CaM), or a fragment thereof by restoring the activity of the catalytic domain of the *Bordetella pertussis* adenylate cyclase (CyaA)” obviates this rejection as to claim 100 and claims 101-105, which depend from claim 100. Accordingly, Applicants respectfully request that this rejection be withdrawn.

#### **IV. Rejections Under 35 U.S.C. § 112, First Paragraph**

##### **A. Enablement**

The Office rejected claims 96-107 under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. While the Office acknowledged the Deposit Declaration of Danielle Berneman, filed July 26, 2004, the Office indicated that the Declaration did not satisfy the enablement requirement because it did not state that “the cells will be irrevocably and without restriction or condition [ ] released to the public upon the issuance of the patent.” (Office Action at page 8.) In response, Applicants file a new Deposit Declaration by Danielle Berneman herewith, which includes a statement indicating that “On information and belief, the cells will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent on this application.” Applicants respectfully request that this rejection be withdrawn.

The Office also rejected claim 96 for an alleged lack of enablement, asserting that undue experimentation would be required to practice the full scope of the claim. Applicants disagree, but note that this rejection has been rendered moot by cancellation of claim 96 herein.

**B. Written Description**

The Office rejected claim 96 under 35 U.S.C. § 112, first paragraph, for an alleged insufficient written description. Applicants respectfully disagree with the Office's position, but note that this rejection has been rendered moot by cancellation of claim 96 herein. Applicants respectfully request that this rejection be withdrawn.

**V. Conclusion**

Applicants respectfully submit that entry of this amendment will place claims 97, 98, 100-105, 119-140, and 143-146 in condition for allowance and that this amendment does not raise new issues or necessitate a new search. Applicants courteously request the entry of this amendment and the timely issuance of a Notice of Allowance in this application.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: November 10, 2004

By: 

Kenneth J. Meyers  
Reg. No. 25,146

**Attachments:      Deposit Declaration**



PATENT  
Customer No. 22,852  
Attorney Docket No. 3495.0202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Group Art Unit: 1652
Gouzel KARIMOVA et al.	)	Examiner: Sheridan Swope
Application No.: 09/818,939	)	
Filed: March 28, 2001	)	
For: BACTERIAL TWO-HYBRID SYSTEM	)	
FOR PROTEIN-PROTEIN INTERACTION	)	
SCREENING, NEW STRAINS FOR USE	)	
THEREIN, AND THEIR APPLICATIONS	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DEPOSIT DECLARATION**

I, Danielle Berneman, do hereby declare and say that:

1. I am the Director of the Patent and Inventions Office of the Institut Pasteur in Paris, France, to whom this patent application has been assigned.
2. On information and belief, *E. coli* strains BTH101 and DHM1, disclosed in this application, were deposited on September 10, 1999, under the provisions of the Budapest Treaty at the National Collection of Cultures of Microorganisms (C.N.C.M.) in Paris, France, and assigned Accession Nos. I-2309 and I-2310, respectively, to assure availability to the public.
3. On information and belief, the C.N.C.M. has acquired the status of International Depository Authority within the meaning of the Budapest Treaty on the

**International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.**


4. Said *E. coli* strains have been deposited under conditions which ensure that access to the strains will be available during the pendency of this patent application to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 1.22.

5. On information and belief, Institut Pasteur will replace the deposited strains BTH101 and DHM1 should they become non-viable during the period that extends thirty (30) years from the date of the deposit, or the period of the enforceable life of the patent, or the period of five years after the last public request for the deposit, whichever period is longest.

6. On information and belief, the cells will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent on this application.

7. I further declare that all statements made herein of my own knowledge are true; that all statements made on information and belief are believed to be true; that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 5<sup>th</sup> day of March, 2004

  
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Danielle Berneman  
Director of Patents and Inventions Office  
Institut Pasteur